

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Soley Bjornsdottir, Augustine Kong and Thorgeir E. Thorgeirsson

Application No.: 10/571,865 Group: 1634

Filed (371(c)): March 14, 2006 Examiner: S.T. Kapushoc

Confirmation No.: 6960

For: INVERSION ON CHROMOSOME 8P23 IS A RISK FACTOR FOR
ANXIETY DISORDERS, DEPRESSION AND BIPOLAR DISORDERS



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REPLY TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Office Communication dated January 8, 2009, the claims of Group 1 (Claims 56-69), drawn to a method of diagnosing a psychiatric disorder, are elected for prosecution. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the non-elected inventions. Applicants do not hereby abandon or waive any rights in the non-elected inventions.

Applicants provisionally elect genetic marker SG08S71 as the species for searching purposes. Claims readable on the elected species are 56-68.

Applicants note that during a telephone conversation between Alice O. Carroll and the Examiner on January 14, 2009, the Examiner indicated that selection of a single marker would be fully responsive to the Restriction Requirement. Applicants further note that this appears to indicate that the Reply to Restriction Requirement that was previously filed on April 2, 2008,

was fully responsive as it elected a single marker. The Specification and claims support a single marker (see, e.g., Claim 62, "one or more markers").

Applicant's traversal of the lack of unity of invention restriction requirement is set forth below.

Lack of Unity Restriction Requirement

The pending claims are subject to a three way restriction requirement as the examiner finds the claims are not so linked as to form a single general inventive concept under PCT Rule 13.1. It is respectfully noted that the instant application is the US national stage application of PCT/US04/30699. The PCT found there to be no unity of invention issues raised with the claims. Applicants question how the US PTO can now raise unity of invention issues at this stage when the PCT, well versed in the unity rules, did not raise this during the PCT stage. Moreover, the PCT did not find there to be any unity issues among claims drawn to methods of diagnosis, kits and method for predicting the efficacy of a drug. Applicants believe that all pending claims should be examined in accordance with the PCT determination that there were no unity issues raised.

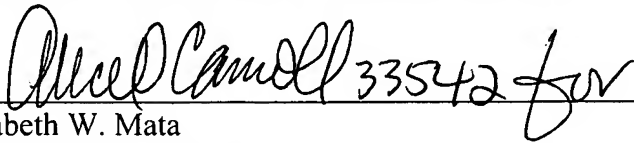
The unifying concept is not, as is stated in the Office Action, solely the inversion of 8p23. Rather, the unifying concept relates to Applicants' discovery that the orientation of Inv8p23 is indicative of susceptibility to a psychiatric disorder or comorbid disorder. Although the Graw *et al.* reference (Am. J. Hum. Genet. 66:1138-1144 (2000)) cited by the Examiner describes an inversion of the 9p23 region, it does not describe or suggest any relationship between a psychiatric disorder or comorbid disorder and the inversion of 8p23.

The markers or combination of markers or haplotypes described in the application represent various tools that the scientist can use, for example in methods as in Groups I and III or in kits as in Group II, to detect the orientation of Inv8p23, where the orientation is indicative of a susceptibility to a psychiatric disorder or comorbid disorder, or is indicative of the efficacy of a drug for treating the psychiatric disorder or comorbid disorder. Each of the groups set forth by the Examiner relates to the relationship between the orientation of the Inv8p23 region and a psychiatric disorder or comorbid disorder. Therefore, Applicants respectfully request that Groups 2 and 3 be examined together with the elected claims of Group 1.

Applicants understand the requirement of selection of a combination of markers to be a species election where the non-elected species will be examined if the provisionally elected species is found patentable. If the election is not a species election, Applicants respectfully note that the restriction requirement for lack of unity is improper for all of the reasons presented above. In view of a clear unifying concept present in all of the pending claims, the lack of unity restriction requirement should be respectfully withdrawn.

Respectfully submitted,

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